

IV. Overview of the Implementation Plan

This section introduces the proposed methodology for developing the initiative to create a national research database linking WIC, Medicaid and vital records data. Specifically, it provides information about the key individuals that will need to be involved in the initiative, an overview of the activities that must take place, and potential implementation barriers.

It is very important to note that the success of this initiative is dependent on a significant amount of “up-front” work on the part of federal and State officials. By bringing together experts in the area of data linkages, persons with experience using linked WIC data for research purposes, and experts in maternal and child health, a number of difficult factors can be dealt with in advance of presenting the initiative to the States. Specific challenges that can be mitigated by such up-front cooperation and deliberation are discussed in Section C.

A. Description of Key Actors

When designing an initiative that involves programs administered through two Federal Departments and three separate state-level agencies, it is critical to identify key players for both the design and oversight of the initiative as well as the implementation phase. This initiative is designed to bring together experts from the key federal and state agencies, as well as national organizations representing State agencies, for the design and oversight portion of the project. Once the implementation phase begins, additional actors will become involved, as State WIC programs work with their Medicaid and Vital Records directors to coordinate data merging and submission. Specific actors and their roles include:

1. USDA Staff

Staff from USDA will be responsible for coordinating this initiative and providing guidance to other key players. Specifically, staff from USDA will be responsible for:

- Identifying key Federal and State officials to participate in the planning and oversight of the initiative;
- Conducting meetings with key constituent and oversight groups in order to develop and implement the initiative;
- Developing, in conjunction with HHS officials, the model data sharing agreement by which the individual programs in each state (WIC, Medicaid, Vital Records) can share their data with one-another.
- Develop the sampling plan for data collection;

- Identifying the key data elements that will be included in the database, and developing the database structure;
- Identifying appropriate methods by which data can be linked and submitted to USDA or other appropriate Federal agency;
- Testing the linkage methodologies, data base development, and data submission protocols;
- Obtaining OMB clearance, if necessary;
- Providing technical assistance to States during the implementation phase of the project;
- Making the database accessible to researchers and State agency officials; and
- Overseeing quality control and storage of the data.

2. Officials from the Department of Health and Human Services.

Because this initiative utilizes data from three different sources, it will be important for officials located within the Department of Health and Human Services to be involved in this project. Specifically, it will be important to have representatives from the National Center for Health Statistics and the Health Care Financing Administration involved in the project. In addition, USDA may wish to involve officials from the Maternal and Child Health Bureau, as they have experience with using Medicaid and vital records data for evaluation purposes. The specific activities in which these federal officials will be involved include:

- Assisting USDA officials with providing overall guidance to State agencies;
- Helping to draft a model data sharing agreement for use by State programs;
- Participating in oversight committee meetings during the development and implementation phase; and
- Providing support and assistance to USDA and State agencies in order to resolve issues that may arise during the testing and implementation phases.

It is important to note that funding issues will likely arise from these meetings. It is anticipated that there will be interest on the part of HHS officials in being able to utilize this database to promote research into achieving such departmental objectives as the Healthy People 2010 goals. In addition, during the 2000 federal fiscal year, the Maternal and Child Health Bureau funded grants to State health departments and research institutions to examine methods by which public health programs could overcome racial/ethnic disparities in access to health care. A number of these grantees proposed

developing links between WIC program data and vital records/Medicaid data (MCH Bureau grant announcements, 2001). It therefore will likely be prudent to include in the discussions between HHS and USDA the notion of joint funding of this initiative.

3. Representatives from State Associations of Program Directors.

In order to gain the cooperation of State officials, it will be critical to involve representatives from each of the three programs in the early developmental stages of this initiative. Each of the three programs involved have associations composed of State program directors. Asking each of these three associations to participate in the developmental stages will be key to gaining state support during the testing and implementation phases. Specific responsibilities of the State association representatives will include:

- Providing advice and technical consultation to Federal officials during the developmental stages of the initiative;
- Attending meetings of the developmental and oversight committees in order to represent the interests of State officials;
- Provide feedback to State officials through the normal channels used by the associations for communicating with their membership; and
- Providing support to the federal agencies during the testing and implementation phases of the initiative.

4. State Program Directors

Much of the testing and implementation of this initiative will be the responsibility of the State WIC directors and their counterparts in the Medicaid and Vital Records programs. It is assumed that the State WIC programs will take the lead in coordinating state-level activities, including developing data sharing agreements, arranging for obtaining data from the other two programs, conducting the data merge, and submitting data to USDA. Specific responsibilities include:

- Developing data sharing agreements with State Medicaid programs and offices administering the State's vital records ;
- Implementing the database structure to be compatible with the State's WIC data system so data can be merged;
- Conduct the data merge and create the datafiles for submission;
- Obtain State-level clearances required by State human subjects review committees;

- Conduct data quality edits and updates prior to submission of data; and
- Submission of data to USDA

B. Overview of Activities

On the surface, this initiative seems feasible because it requires no new data collection on the part of State agencies. However, because this initiative requires the cooperation of so many agencies and officials, it will require a significant amount of preliminary activities, planning, and testing prior to implementation. This initiative will likely take from two to two and one-half years to implement. Detailed tasks involved in the planning and implementation of this initiative are contained in Section V.

It is envisioned that the initiative will be developed and implemented in three phases. These phases include:

- A preliminary phase that will bring together all of the major players in the initiative and develop a shared vision of the project, its goals, and its methodology. The preliminary phases will require that officials both agree to cooperate with the initiative and commit to providing their time and expertise in the developmental and implementation phases.
- A developmental phase, in which after all parties agree to the value of pursuing the initiative, the basic logistical and technical issues will be developed. This phase will include the development of model data sharing agreements, identification of data elements and development of the basic database that will be created for the merged data set, development of the data merging protocols and the programs necessary to implement the data merge, and development of quality control, data access, and data storage protocols. Activities will need to occur at both the State and Federal level during this phase, and by its end the mechanisms should be in place to begin testing and implementation of the initiative.
- An implementation schedule, which will begin with testing the developed data merging protocols, database integrity, and the data submission protocols. Refinements will need to be made once the initial testing is complete, and a second round of testing will be likely. Once the testing phase is complete, and implementation schedule will need to be developed and submitted to the States.

Much of the time-consuming work will be involved in the developmental phase, and will involve obtaining agreement and cooperation from the multitude of Federal and State officials involved. In addition it will be important to provide States WIC officials with assurances that this initiative will not be a significant added burden to their workload.

In order to properly implement this initiative, a steering committee will need to be organized to oversee each of the phases of the initiative, and, at times, may involve different individuals depending upon the task being undertaken. For example, while a State WIC director may wish to participate in the preliminary and planning phases, they may wish to have a technical person participate in activities involving the development of the database structure and data merging activities. Therefore, it is envisioned that a steering committee to oversee the phases will be developed, some of the players may change as the initiative progresses.

C. Potential Barriers to Implementation

Some limitations and potential difficulties in developing this initiative also need to be considered before deciding to proceed.

1. ***The Complexity of the Data Links.*** While it has been noted previously that several States have been successful in linking WIC, Medicaid, and vital records data, this is still a complex process when expanded across all States. This initiative proposes to use the expertise of numerous individuals who have had experience in linking data files to both develop the content and structure of the database as well as develop the protocols for linking the data. Because data can not be linked through a single identifier, an algorithm utilizing demographic information will be used to create the links. The algorithm will need to be tested and refined prior to utilizing it as the method by which files will be linked in each State. Once in place, however, the future data links should be much easier to accomplish.

One other factor must also be considered, which is the technical feasibility of State systems to link the records. It is important to note that States are consistently refining their State WIC program data systems, and, in many cases, have included systems by which linking WIC with Medicaid and vital records data will be easier. For example, North Carolina, South Carolina, California, Massachusetts, and Illinois identify Medicaid participation in their WIC files. Recent RFPs for North Dakota, Iowa and Maryland propose to capture data to improve linkages. We believe that improvements in State data systems, including the movement to Internet-based systems, will make the feasibility of data linkages easier.

2. ***Obtaining the Cooperation of State Agencies.*** State agency's initial reaction to this initiative may be to express concerns regarding the perceived burden they will incur to make the initiative successful. However, it must be noted that given the interest expressed by State officials regarding the importance and need for outcome information regarding WIC program participation and program dynamics, the existing system places a far greater burden on States than would a structure approach proposed in this initiative. The number of States that currently

link data further supports this. Under the existing system, data are collected and used for a single individual study. This means that any time additional information is needed, or additional research projects are funded, States must undergo the burdensome process of cooperating with the new study. By conducting a data linkage every two years, as proposed in this initiative, multiple research projects can be undertaken by federal and state officials, without requiring state cooperation and involvement in each individual research effort.

3. ***Overcoming Administrative Barriers.*** One of the key implementation parameter to consider in terms of project time and effort needed to enact this initiative is the fact that there are both technical and administrative pieces requiring time and effort on the part of those involved. In most cases, the technical components will likely be less difficult to design and implement in comparison to the time-consuming administrative process that will be necessary to obtain cooperation and approval from all of the key players. As was noted earlier, the up-front efforts to develop this initiative are critical to its acceptance and success. It is anticipated that there will need to be a review of the initiative's progress at different stages to decide if full implementation is still possible, or if alternatives will need to be considered

4. ***Limitations of Vital Records Data.*** Vital records data reflect only the births within a given State, so some WIC and Medicaid data will not be able to be linked to these data. In the studies cited earlier in the States of Missouri and North Carolina, the main reason cited for non-matching records was the fact that some WIC infants were born out-of-state, and therefore were not included in the vital records database. While both North Carolina and Missouri showed relatively high match rates (over 95%), this may be more problematic in States with more migrant populations.

5. ***Creating Data Sharing Agreements.*** One of the key issues identified by State WIC agencies in trying to link data records is the need to develop data sharing agreements. This is particularly important since the passage of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which enhances privacy, rights of individuals receiving health care. The custodians of the WIC, Medicaid, and vital records data all face limitations as to how their data can be used, and by whom. However, States are addressing this issue through the modification of existing data sharing agreements. For example, the Massachusetts WIC and Medicaid programs recently worked with their Attorney General's office to revise their data sharing agreement to address HIPAA concerns. Both Missouri and Iowa are currently working on revising data sharing agreements and

consent forms to allow for the continued linkage of WIC, Medicaid and vital records data.

It would be very helpful to States for USDA to take the lead in working with States who successfully addressed the HIPAA issues to develop model data sharing agreements. This initiative envisions USDA working with selected States, along with several divisions of the Department of Health and Human Services on this initiative. These players would include the National Center for Health Statistics, the Health Care Financing Administration, and the Maternal and Child Health Bureau. While the idea of cooperation between the two departments is reasonable, the resulting need to coordinate may slow the process down.

6. ***Use of Managed Care Plans by State Medicaid Agencies.*** Because some State Medicaid programs use managed care plans for delivering health services, there will be limited encounter data available on individual client medical visits. Traditional Medicaid encounter data includes information on the type of services provided to the client. However, because managed care plans are not required to bill for individual visits, the specific encounter data is usually not available in the State's Medicaid data file. Researchers would still be able to use Medicaid enrollment data to examine program participation and dynamics issues. In addition, most states required managed care plans to report on certain basic health services, such as EPSDT services, pre-natal care information, and the immunization status of children enrolled in the plan. This information would be useful in examining some of the program outcomes of interest to USDA. Finally, as was demonstrated in the Detroit study, linkage of managed care data and WIC data with birth records can also examine birth outcomes in managed care settings as compared to traditional primary care providers.
7. ***Client Confidentiality Issues.*** There may be concerns expressed by individual State WIC Directors with regard to client confidentiality. This is likely to be a result of traditional concerns combined with HIPAA regulations. It is important to note that this initiative proposes to strip off any client identifying information prior to making the data available for research purposes. This issue must be addressed when the data sharing agreements noted above are developed by the individual states. In addition, we propose to develop model data sharing agreements and consent forms that can address HIPAA issues, which will help States to overcome administrative barriers associated with client confidentiality. It is important to note that the data being asked for from the WIC program is data that is already collected and submitted to USDA for the WIC Program Participant Characteristics database. While the linkages with vital records and Medicaid may result in additional concerns, the fact that

several states currently or in the recent past have overcome privacy issues should be considered encouraging and not insurmountable.